K123452

stryker®
Neurovascular

JAN 0 3 2013

510(k) Summary

Summary Date December 03, 2012

Submitter Name and Address
Stryker Neurovascular
47900 Bayside Parkway
Fremont, CA. 94538

Contact Person:
Jean Chen
Regulatory Affairs Specialist I
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Trade Name: Tracker®-17 Microcatheter

Common Name: Percutaneous Catheter; Microcatheter

Classification Name: Percutaneous catheters are currently classified as Class II devices per 21 CFR 870.1250. No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for these devices.

Legally Marketed Predicate Device:

Reference (Clearance Date)	Device
K994155 (3 Aug 2010)	Tracker Excel-14 Microcatheters

Device Description:

Stryker Neurovascular's **Tracker-17 Microcatheter** is a single lumen device designed to aid the physician in accessing distal vasculature when used with a guiding catheter and steerable guidewire. Graded shaft stiffness ranging from a highly flexible tip to a semi-rigid proximal section aids the physician in tracking over selectively placed guidewires. A luer fitting located on the microcatheter hub is used for the attachment of accessories. A radiopaque tip facilitates fluoroscopic visualization. Hydrophilically coated Reinforced Microcatheters are coated on the outer surface with Hydrolene™ Coating that reduces friction during manipulation in the vessel.

Accessories:

Tracker-17 Microcatheters are packaged with a steam shaping mandrel as an accessory.

Indications for Use / Intended Use:

Stryker Neurovascular's Tracker-17 Microcatheters are intended to assist in the delivery of diagnostic agents, such as contrast media, and therapeutic agents, such as occlusion coils, into the peripheral, coronary and neuro vasculature.[3]

Technological Characteristics and Product Feature Comparison:

Stryker Neurovascular's Tracker-17 Microcatheter is substantially equivalent to the predicate device in terms of

- functionality
- method of operation
- intended use
- indication for use
- biological safety

A tabular comparison of the specific technological characteristics between the predicate device and the proposed device is provided below.

[3] Please note, the peripheral and coronary indications are currently not included on the labeling materials because of a contractual agreement Stryker Neurovascular has with Boston Scientific.

510(k) Summary (cont.)

Product feature comparison for the Tracker-17 Microcatheter

Characteristics	Results
Shaft Material Proximal	Offered with Pebax as compared to the predicate device, which was cleared with Carbothane proximal shaft material.
Shaft Material Mid	Same as predicate.
Shaft Material Distal	Same as predicate.
Shaft Design	Same as predicate.
Distal Shaft Length	Same as predicate.
Mid shaft length	Same as predicate.
Mid transition length	Same as predicate.
Proximal shaft length	Same as predicate.
Proximal ID/OD	Same as predicate.
Distal ID/OD	Same as predicate.
Tip Marker	Same as predicate.
Coating	Same as predicate.
Effective Length	Same as predicate.
Hydrolene Uncoated length	Uncoated length of proximal shaft has increased from 35 cm to 50 cm.
Indication	Same as predicate.
Sterilization Method	Same as predicate.
Packaging Material	Same as predicate.
Packaging Artwork	Offered as Stryker branded products.
Packaging Carton	Offered with perforated opening, as compared to the flap-insert opening.
Closure Strip	Offered with smaller packaging closure strip without slits compared to the predicate device.

Risk assessment of the modifications in the form of Design and Use FMEAs has been conducted in accordance with EN ISO 14971:2012. Stryker Neurovascular has determined the modifications to the predicate device raise no new questions of safety or effectiveness.

Results of verification testing have demonstrated the Tracker-17 Microcatheters are substantially equivalent to the predicate Tracker Excel-14 Microcatheters.

Conclusion:

Because the subject modifications do not alter the intended use or indications for use of the predicate device, or the fundamental scientific technology of the predicate device; and because risk assessment of the modifications and successful verification testing raise no new questions of safety and effectiveness, Stryker Neurovascular has determined the Tracker-17 Microcatheters to be substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 3, 2013

Stryker Neurovascular
Ms. Jean Chen
Regulatory Affairs Specialist
47900 Bayside Parkway
Fremont, CA 94538

Re: K123452
Trade/Device Name: Tracker-17 Microcatheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: December 3, 2012
Received: December 5, 2012

Dear Ms. Chen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang

for Victor Krauthamer, Ph.D.
Acting Division Director
Division of Neurological and Physical
Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K123452

Device Name: Tracker-17 Microcatheter

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Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joyce M. Whang

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

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